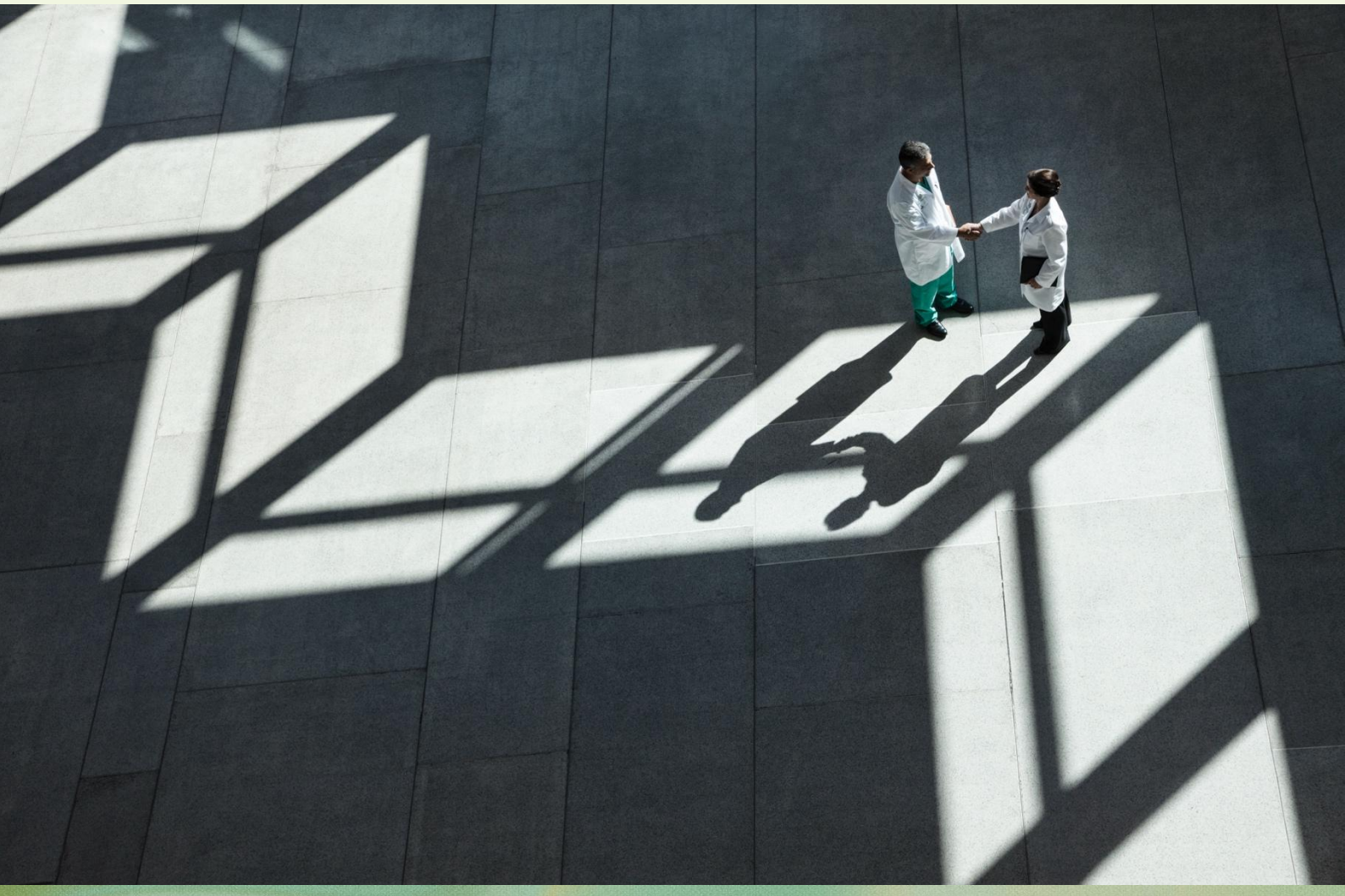
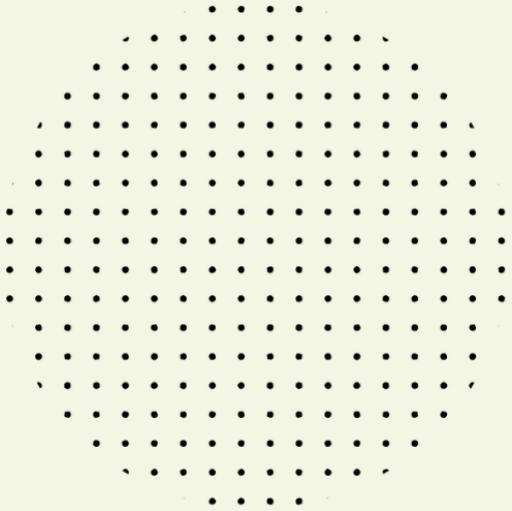
Market Research & Consulting
SEED PLANNING

Japan's Drug Reimbursement and Pricing Process

Structure and Stakeholders





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Overview

Japan operates a universal National Health Insurance (NHI) system where drug prices and reimbursement are centrally regulated. Unlike in the US, private insurers in Japan do *not* independently determine drug coverage or pricing. Instead, a government-led process involving multiple stakeholders ensures that once a drug is approved, it is evaluated for reimbursement and priced uniformly nationwide. Below, we break down the key organizations and steps in Japan's drug reimbursement process, and why understanding physician perspectives is crucial for pharma market research in Japan.

1. Key Stakeholders and Their Roles in Reimbursement

- **Chuikyo (Central Social Insurance Medical Council):** A government advisory council that determines which medical services and drugs are covered by NHI and at what price. Chuikyo plays a central role in price setting, advising the Ministry of Health on official reimbursement prices. It is a tripartite body composed of payer representatives (e.g. health insurers, employers, patient group voices), provider representatives (e.g. physicians' and hospitals' associations), and public interest experts. This mix ensures both the payers' budget perspective and providers' clinical perspective are considered in pricing decisions. A former Chuikyo member (2015–2021) noted that the council's role includes debating coverage of new drugs, especially high-cost therapies, to balance patient needs with the national insurance budget.

  Ultimately, Chuikyo decides whether a newly approved drug should be admitted to the NHI formulary (covered by insurance) and endorses an official price for it.

- **Yakka Senmon Bukai (Drug Pricing Subcommittee):** A specialized drug pricing subcommittee that operates under or alongside Chuikyo. This expert committee conducts a scientific assessment of new drugs' clinical value and appropriate price before final listing approval. It reviews the drug's safety, efficacy, and comparable therapies, and proposes a draft reimbursement price. In practice, once a new drug is approved by regulators, the subcommittee evaluates the evidence and calculates a price using predefined rules (comparator-based or cost- based) . The subcommittee's evaluation is reported to Chuikyo, and Chuikyo generally respects this report – it does not redo the clinical evaluation, but focuses on the policy decision of whether the drug should be covered by insurance.

Essentially, if the subcommittee deems a drug safe, effective, and assigns a price, Chuikyo's task is to decide if that drug enters the NHI list or remains uninsured (private pay) . In recent years, this process has become critical for ultra- expensive drugs: the subcommittee's rigorous review provides assurance that a drug has value, and Chuikyo then weighs if covering it is feasible for the system.

- **MHLW (Ministry of Health, Labour and Welfare):** The government ministry overseeing Japan's health policy and insurance system. MHLW officially sets drug prices and coverage decisions but does so based on Chuikyo's recommendations. In fact, by law the prices of healthcare services and drugs are those "the Minister of MHLW specifies," following the advice of Chuikyo. MHLW's Health Insurance Bureau and Economic Affairs Division coordinate the pricing process – negotiating with pharmaceutical companies, convening the expert subcommittee meetings, and preparing price proposals in line with rules. MHLW ensures that once Chuikyo approves a drug for coverage, it is listed in the NHI Drug Price List (the nationwide formulary) with a uniform reimbursement price. MHLW also controls the schedule of price listings and periodic price revisions. Important: Manufacturers in Japan cannot set their own drug prices; any drug to be reimbursed must go through this government pricing process.
- **PMDA (Pharmaceuticals and Medical Devices Agency):** Japan's regulatory authority (akin to the FDA) responsible for reviewing new drugs for quality, safety, and efficacy. A pharmaceutical company must obtain PMDA approval (marketing authorization) before any reimbursement decision is considered. PMDA's role is *only* the scientific/regulatory approval of the drug itself; it does not decide if the drug will be covered by insurance. However, PMDA approval is the prerequisite first step in the pathway. Once PMDA approves a drug, the baton passes to the pricing authorities. (Notably, there is coordination in the sense that PMDA and MHLW experts may advise companies on data requirements to facilitate eventual reimbursement, but PMDA is not directly involved in pricing.)

2. Process from Approval to NHI Listing

Once a new drug is approved by the PMDA, Japan's system moves quickly to evaluate it for reimbursement. Listings of new drugs occur up to four times a year on a regular schedule, and by policy a drug is usually added to the NHI list within 60 days (no later than 90 days) of regulatory approval, provided there are no pricing disputes. Below is an overview of the end-to- end process from regulatory approval to pricing and NHI inclusion: The manufacturer may be invited to present information or clarify data during this process. If the manufacturer disagrees strongly with the

draft price, there is a short window to contest and provide further justification, but in general the subcommittee's calculation follows established rules transparently.

From PMDA Approval to NHI Reimbursement (Japan) — 2026

1) PMDA Regulatory Approval

PMDA grants marketing authorization (quality, safety, efficacy).

2) NHI Listing Application & Pricing Kickoff (MHLW)

Manufacturer submits listing request to MHLW.

Target timeline: ≤ 60 days (≤ 90 days max) from approval.

3) Drug Pricing Subcommittee (Yakka Senmon Bukai)

Determines draft NHI price using:

- Similar Efficacy Comparison, or
- Cost Calculation (cost-plus).

Considers premiums (e.g., innovativeness, market size).

4) Chuikyo Deliberation & Decision

Tripartite council (payers, providers, public).

Approves coverage and endorses price.

May require Optimal Use Guideline for select high-cost/innovative drugs.

5) Official NHI Price Listing

Drug added to NHI Drug Price List on scheduled listing dates.

Uniform national price; reimbursable nationwide.

6) Post-listing Cost-Effectiveness Evaluation

For high-impact drugs, CEA is conducted post-listing.

Results can trigger price adjustment (down/up).

7) Periodic Price Revisions

Biennial revisions + interim adjustments based on market prices.

Lifecycle price management under Chuikyo/MHLW.

Timelines & Cadence

- Listing target ≤60 days (≤90 days max) from approval
- Listing schedule: 4×/yr → 7×/yr (from FY2025)

Sources: MHLW/Chuikyo on 60/90-day listing; PMDA NHI Drug Price System; Chuikyo/C2H on post-listing CEA; FY2025 listing cadence updates.

Figure: Illustration of Japan's drug pricing algorithm (Similar Efficacy Comparison method). If Drug A is a new therapy similar to an existing Drug B, Drug A's price is set equal to Drug B's price for fairness. If Drug A offers superior efficacy or safety, a premium (e.g. +10%) may be added to reward its added benefit. If no comparator exists, a cost-plus formula is used. This system ensures new drugs are priced in line with their clinical value and cost, rather than allowing free pricing.

- **Chuikyo Deliberation and Approval:** The draft price and recommendation from the subcommittee are then reviewed by the Chuikyo council in a formal session. In these meetings, Chuikyo members (representing payers, providers, and public interest) discuss whether the drug should be included in the NHI reimbursement list at the proposed price. They consider factors such as the clinical need for the drug in Japan, the budget impact at the proposed price, and any broader policy concerns. This is where the payer side (insurer representatives) may voice worries about cost sustainability, while the provider side (physicians) emphasizes clinical importance. In practice, by the time it reaches Chuikyo, the drug has passed safety/effectiveness checks and a price is calculated, so Chuikyo often focuses on coverage justification – essentially, can we afford to cover this drug and is it in the public interest to do so. It is rare for Chuikyo to outright reject listing a drug that the expert subcommittee cleared; a former Chuikyo member noted that in his 6-year tenure, *every* new drug evaluated was ultimately approved for coverage. Nonetheless, high-profile cases have sparked intense debate – for example, a very expensive oncology therapy prompted discussion that if reimbursed at a very high price, it could "bankrupt" the insurance system, yet Chuikyo members concluded it should be covered because of its necessity for patients. Chuikyo may also set conditions for use if needed (such as requiring the creation of optimal use guidelines, see below). Once Chuikyo votes in favor, the decision is passed to the health minister.

- **Official NHI Price Listing:** With Chuikyo's endorsement, MHLW formally lists the new drug on the NHI Drug Price List at the agreed price. This means the drug is now reimbursable under every public health insurance plan in Japan. The listing usually occurs at the next quarterly update of the NHI price list (Japan aligns new listings to a quarterly cycle) . From that date, any physician in Japan can prescribe the drug and it will be covered by insurance (with patients paying the standard copayment, typically 30%, and insurers/government paying the rest). The NHI Drug Price List entry includes the drug's name, form, price per unit, and any special notes (for example, if an "optimal use guideline" is mandated, or if the drug is restricted to hospital use). The uniform pricing means every hospital and clinic is

reimbursed at the same rate, and manufacturers cannot charge more than the listed price. This centralized listing ensures equity – all patients nationwide have access to the new medicine at the same price, avoiding regional or insurer differences.

- **Post-listing Cost-Effectiveness Evaluation (select cases):** In 2019, Japan introduced a formal health technology assessment (HTA) step for extremely costly or innovative drugs *after* they are listed. Chuikyo will flag certain new drugs (usually those with very high budget impact or uncertain value) for a cost-effectiveness analysis (CEA). In these cases, the manufacturer must submit a pharmacoeconomic dossier (within ~9 months of listing) to a specialized body (C2H, Center for Outcomes Research and Economic Evaluation). The cost/QALY and other metrics are reviewed over ~6 months, and Chuikyo then uses the results to decide if the drug's price should be adjusted. If a drug is found to have poor cost-effectiveness (i.e., the price is too high relative to its health benefit), Chuikyo can mandate a price cut (often on the order of 5– 15%). This happened recently for a new Alzheimer's disease drug that was judged to have a modest benefit at a very high cost – its NHI price was cut by about 15% after CEA. (Conversely, if a drug was priced conservatively and shows exceptional value, there is a mechanism to increase its price, though this is rare.) The CEA process ensures long-term value for money, but importantly it *occurs after the drug is already available* to patients. This reflects Japan's approach: provide timely access (don't delay listing), then later adjust the price if needed for sustainability.

- **Periodic Price Revisions:** All reimbursed drug prices are subject to periodic revisions (usually every 2 years, aligned with overall NHI fee schedule revisions, plus special annual cuts for drugs with large sales). This is not an active step in initial reimbursement, but it's part of the system's lifecycle: Chuikyo regularly reviews market prices and will reduce NHI prices of drugs if market prices have fallen or if the drug's sales vastly exceed projections. This is done to control costs and is another way payers' concerns are addressed collectively. Pharmaceutical companies thus face an environment of initial price controls and ongoing adjustments, rather than free pricing.

3. Why Japan Lacks US-Style Payers: Institutional "Payer" Role in Chuikyo

One striking difference in Japan is the absence of separate payer entities like U.S. insurance companies that individually negotiate prices or decide on drug formularies. In Japan's NHI system, all key reimbursement decisions are centralized through MHLW and Chuikyo. Health insurance societies (the "payers") do not have the authority to cover or deny specific drugs – any drug listed on the NHI price list must be covered by all insurers. The benefit package is uniform nationwide, defined by the government. Thus, there is no concept of one insurer covering Drug X while another does not; coverage decisions are made once at the national level.

- **Institutional Payer Representation:** Instead of separate payer organizations making coverage calls, Japan embeds the payer perspective within Chuikyo. The council's payer-side members include representatives from insurance providers (e.g. the Japan Health Insurance Association, employer health insurance societies, mutual aid), business associations, and sometimes patient advocacy groups. Their mandate is to advocate for cost containment and the financial sustainability of the NHI fund. In Chuikyo meetings, these payer reps scrutinize the economic impact of new drugs and push back on prices they deem too high. For example, as mentioned, they may raise alarms that covering a ultra- expensive drug could strain the system. On the other side of the table, medical provider reps argue for patient access and fair compensation for new technologies. This built-in adversarial collaboration replaces the market-driven negotiations seen in the US. The end result (a single coverage and price decision) is a compromise reached under government oversight, rather than a patchwork of private insurer decisions.

- **No Independent Payer Decision-Making:** Because of this structure, Japan has no analog to U.S. insurance formularies or pharmacy benefit managers. Public insurers in Japan are not-for-profit entities required to follow government-set policies; they cannot design their own drug benefit or negotiate separate prices with manufacturers. All they do is administer the claims according to the uniform fee schedule and drug price list. They also cannot exclude patients or treatments – by law they must cover all medically necessary services on the NHI list. In practice, this means once Chuikyo lists a drug, every insurer (whether national employee insurance, residence-based insurance, etc.) will reimburse it at the fixed price. There is no need for individual insurers to perform cost-effectiveness analyses or coverage reviews; Chuikyo has done it for the entire system.

- **Implications:** Without independent payer decision-makers, the locus of decision-making is Chuikyo itself. Chuikyo's decision is final and applies universally. The "payer" role is thus *institutionally embedded* in that council – it's a consensus-driven form of what in other countries might be a negotiation between payer and manufacturer. This greatly simplifies market access in Japan (one national evaluation instead of many private ones) but also means pharmaceutical companies have little leverage – they cannot play one insurer against another or offer discounts in exchange for formulary placement (discounting in Japan happens via mandatory price cuts, not private rebates). It also means that market research or engagement with "payers" in Japan is limited. Unlike in the US or EU where pharma might talk to insurance P&T committees or payers, in Japan the relevant forum is Chuikyo and its subcommittees, which are government-run. Additionally, employees of Japan's public insurance bodies are often civil servants or bound by strict rules – they generally do not participate in outside meetings or research that could influence policy, and they must enforce the policies as given. In fact, industry experts note that it is difficult to conduct "payer research" in Japan because insurance officials have little flexibility or information to share beyond the official public stance.

In summary, Japan lacks separate payer stakeholders with decision power because the system itself is the payer. The government (through MHLW/Chuikyo) acts as the single payer, setting one price and one set of rules for all. This model eliminates the need for individual payers to make coverage decisions – their role is collectively exercised in Chuikyo's deliberations. The focus of power in reimbursement is therefore on the regulatory and policy bodies rather than on insurance companies or hospital insurers as independent entities.

4. Why Physicians Are the Key Stakeholders for Drug Value and Access

Given the above, once a drug is listed for reimbursement in Japan, there is no further gatekeeper deciding whether a patient gets it – the deciding factor is the physician's prescription. Doctors in Japan have nearly universal prescribing authority within the bounds of approved indications and any guidelines. There are no insurance prior authorizations or insurer-imposed formulary restrictions for drugs on the NHI list. Therefore, from a market research and strategy standpoint, physicians (especially prescribers in the relevant specialty) are the most critical stakeholders to understand when evaluating a drug's utilization, perceived value, and drivers of prescription.

Several reasons underscore the primacy of physicians over payers in Japan:

- **Uniform Coverage Means Physician Choice Drives Utilization:** If a drug is on the NHI list, any licensed physician can generally prescribe it and expect reimbursement. Patients can go to any hospital or clinic, and providers are reimbursed by the national insurance for that drug. There is no variation by region or insurer. Thus, the main variable in whether a drug is used is whether doctors choose to use it in practice. A drug with great clinical merit but physician hesitancy will have low uptake, whereas a drug that physicians favor will be widely used – the insurer will always pay as long as it's on the list. Unlike in the US, doctors don't need to worry about which insurance covers which drug; they focus on clinical factors. This means physicians' opinions on a drug's effectiveness, safety, and necessity will directly influence how often it is prescribed and how patients benefit, without an intermediate layer of payer approval.

- **No Active Role for Insurers Post-Listing:** Insurance institutions in Japan do not perform ongoing management of specific drugs. They cannot refuse payment for an NHI-listed drug, nor can they institute their own usage management criteria (such as step therapy or quantity limits) – those would violate the national coverage rules. Their role is largely administrative: processing claims and funding the care. Moreover, officials from these payer organizations are generally not accessible for consultation – they rarely engage in market research interviews, and if they do, they are constrained in what they can say. As a result, gaining insights from "payers" in Japan yields little actionable information; they will simply reiterate national policy (e.g. "if it's listed, we pay for it; if not, we don't"). Any nuanced

insight on drug positioning, value assessment, or likely prescribing hurdles must come from the medical community, not the payers.

- **Physicians as Decision-Makers on Value:** In Japan's system, evaluating a drug's "value" (clinical benefit relative to other options) is primarily a clinical question handled by experts and, increasingly, by health technology assessment at a system level. But on the ground, it is physicians who interpret a drug's value when deciding to prescribe. For example, how do doctors view the new drug's efficacy? Does it address an unmet need in their patients? Are they comfortable with its safety profile? These perceptions determine whether the drug becomes a first-line choice, a last-resort, or is avoided altogether. Since pricing is fixed and patient cost- sharing is mostly fixed (typically 30% coinsurance), cost is less of a barrier for patients at the point of care – so a physician's recommendation is highly influential in-patient access. In practical terms, to understand a drug's market access in Japan, one must understand physician adoption: their knowledge, attitudes, and any barriers (e.g. need for special monitoring or hospital resources).

- **Guidelines and Institutional Protocols:** Instead of payer-imposed restrictions, Japan manages appropriate use through clinical guidelines and sometimes Ministry-mandated conditions. For some high-cost or high-risk medications, the MHLW issues a "Saiteki Shiyo Guideline" (Optimal Use Guideline) at the time of listing. These guidelines, developed with expert physicians, specify the exact patient criteria and usage conditions for the drug to ensure cost-effective and safe use. For instance, a guideline might state that a certain cancer drug can only be used after failure of standard therapy, or only by physicians certified in its use, or only at hospitals with certain capabilities. This is not an insurer decision – it is a policy decision implemented clinically. Physicians must adhere to these criteria or risk insurance not covering the drug. However, this again places the onus on physicians to follow best practices. It means that in researching the market, one should talk to physicians about how such guidelines affect their prescribing. Do they find the criteria appropriate? Will they readily identify patients who fit the criteria? These are the kinds of questions that determine access in Japan, rather than insurer formulary tiering. Essentially, Japanese physicians and clinical societies are the arbiters of appropriate use, working within broad government rules, rather than payers managing utilization case-by-case.

- **Hospital and Clinic Dynamics:** In Japan, many expensive drugs (like oncology therapies, biologics) are provided in hospital settings. While hospitals do have budgets and are concerned with financial sustainability, under NHI they are reimbursed for drugs at cost (the NHI price), so the drug cost is passed through to the insurer. There isn't a separate "budget impact" negotiation with insurers as in some countries' hospital formularies. Hospitals may have pharmacy & therapeutics (P&T) committees that decide which drugs to stock, but their decisions are often based on clinical merit, guideline inclusion, and reputational factors rather than cost alone (since reimbursement is assured). Therefore, understanding the hospital physicians' and pharmacists' views is key – if they believe a drug is worth it, they will carry and use it (knowing they'll be reimbursed), but if they doubt its benefit or find it operationally difficult, they may restrict it. Once again, the leverage lies with clinical stakeholders, not insurance administrators.

- **Experience and Cultural Context:** Culturally, Japanese healthcare has a strong norm of "open access" – patients can access any covered service, and providers aim to offer needed care without financial barriers at point of service. Physicians are trained and ethically driven to provide the best care within the universal system's coverage. They are aware of cost considerations mainly through the guidance of MHLW (for instance, knowing that very costly drugs are closely watched). In interviews, Japanese doctors often acknowledge cost-pressure on the system, but they see it as the government's job to price and manage it. Their job is to treat the patient. This is fundamentally different from a U.S. physician who might have to consider if an insurer will approve a treatment.

Thus, Japanese physicians' decision-making on drug use is influenced predominantly by clinical factors (efficacy, safety, patient preference, guideline support). For pharma research, this means physician insights will reveal the real-world value perception and barriers – e.g., "Do doctors trust the trial data? Are they comfortable with handling side effects? Do they need more education or experience before adopting the drug?" – whereas payer interviews would not yield such depth.

Supporting Insight: According to experts, payer research in Japan is notoriously challenging and often unproductive, because the payers' role is constrained. As one industry guide notes, Japan's public insurers do not negotiate or select coverage and their staff are usually not allowed to share insights in market research; consequently, *"feasibility for payer studies in Japan is very low"*. On the other hand, engaging with key physicians (and maybe hospital pharmacists or JSMO/JSGE – relevant medical society members) will shed light on how a drug will actually be used in the Japanese market.

Conclusion

Japan's drug reimbursement system is a highly centralized, transparent process that ensures rapid and uniform access to new therapies once approved. The Central Social Insurance Medical Council (Chuikyo), with its blend of payer and provider representatives, serves as the institutional decision-maker for drug pricing and coverage – a role that in other countries is fragmented among insurers, PBMs, and health technology bodies. Pharmaceutical companies entering Japan must navigate this process by demonstrating clinical value to the national committees, rather than negotiating with dozens of private payers. The absence of independent payer barriers means that the success of a new drug in Japan largely hinges on clinical adoption: if the nation's doctors recognize the drug's value and need, it will be used and accessible across the country (with cost covered by insurance); if the clinical community remains skeptical, utilization will lag even though reimbursement is in place.

For pharma stakeholders and researchers, the key takeaways are: focus on the policy process and its timelines (e.g. prepare for Chuikyo evaluation ~2 months post-approval, understand pricing rules) and invest in physician engagement and education, as they are the true drivers of usage. Understanding Japan's unique reimbursement structure – where the "payer" is essentially the state and its advisors – allows companies to tailor their market access strategy: prioritize health-economic evidence for Chuikyo, ensure alignment with Japanese clinical guidelines, and gather insights from physicians about unmet needs and treatment decision factors. By doing so, global pharma companies can better position their products for success in Japan's system, which rewards innovation and clinical value but demands consensus and affordability.

Sources

The information above is derived from an expert interview with a former Chuikyo member, official publications on Japan's drug pricing system and industry research insights.
These sources underscore how Japan's reimbursement process works and why it emphasizes stakeholder consensus and physician-led value assessment over market-driven payer competition.

1) Japan | International Health Care System Profiles | Commonwealth Fund
https://www.commonwealthfund.org/international-health-policy-center/countries/japan
2) Price setting of medicines and medical devices | C2H | Center for Outcomes Research and Economic Evaluation for Health
https://c2h.niph.go.jp/en/assessment/price-setting/
3) Seed Planning interview with Chuikyo Cost-effectiveness analysis in Japan's HTA process
https://petauri.com/insights/cost-effectiveness-analysis-japan/
4) Pharmaceutical Regulations in Japan 2020 - CHAPTER 6. HEALTH INSURANCE PROGRAMS AND DRUG PRICING IN JAPAN
https://www.jpma.or.jp/english/about/parj/eki4g60000007840-att/2020e_ch06.pdf
5) nihs.go.jp
https://www.nihs.go.jp/mhlw/yakuji/yakuji-e_20110502-02.pdf
6) Market Research in Japan: Understanding the Health Insurance System
https://www.m3global.com/blog-understanding-japan-health-insurance-system.html